Complete Summary

GUIDELINE TITLE

Adult immunizations.

BIBLIOGRAPHIC SOURCE(S)

University of Michigan Health System. Adult immunizations. Ann Arbor (MI): University of Michigan Health System; 2009 Feb. 10 p. [8 references]

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: University of Michigan Health System. Adult preventive health care: immunizations. Ann Arbor (MI): University of Michigan Health System; 2008 Apr. 10 p. [8 references]

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

- Diphtheria
- Hepatitis A virus infection
- Hepatitis B virus infection
- Herpes zoster infection
- Human papillomavirus (HPV) infection
- Influenza
- Measles
- Meningococcal meningitis
- Mumps

- Pertussis
- Pneumococcal disease
- Rubella
- Tetanus
- Varicella virus infection

GUIDELINE CATEGORY

Prevention

CLINICAL SPECIALTY

Allergy and Immunology
Family Practice
Geriatrics
Infectious Diseases
Internal Medicine
Obstetrics and Gynecology
Preventive Medicine

INTENDED USERS

Advanced Practice Nurses
Nurses
Pharmacists
Physician Assistants
Physicians
Public Health Departments

GUIDELINE OBJECTIVE(S)

To implement an evidenced-based strategy for routine adult immunizations

TARGET POPULATION

Adults, 18 years and older

INTERVENTIONS AND PRACTICES CONSIDERED

Adult immunizations, including:

1. Hepatitis B vaccine series (Twinrix for combined hepatitis A & B vaccination)
2. Hepatitis A vaccine series (Twinrix for combined hepatitis A & B vaccination)
3. Herpes zoster vaccine
4. Human papilloma virus (HPV) vaccine, Quadrivalent
5. Influenza vaccines
    - Inactivated (injectable)
    - Live attenuated (intranasal)
6. Measles, mumps, rubella (MMR) vaccine
7. Meningococcal vaccine
    - Meningococcal conjugate (Menactra™) for adults <55 years of age

- Meningococcal polysaccharide (Menomune®) for adults >55 years of age

8. Pneumococcal polysaccharide vaccine
9. Tetanus, diphtheria, pertussis (Td/Tdap)
10. Varicella vaccine series

MAJOR OUTCOMES CONSIDERED

- Incidence and prevalence of vaccine-preventable diseases
- Disease-attributable mortality and morbidity
- Adverse effects of vaccines
- Hospitalization for complications

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

The literature search for this update began with the results of the literature search performed in developing the initial version of this guideline. That search on Medline was for literature published from 1/1/05 through 5/1/99. It included the major key words of adults, humans, English; and a number of specific search terms related to immunizations (see specific search terms printed in initial University of Michigan Health System (UMHS) guideline published March, 2004). Since that search additional literature searches for the initial guideline and subsequent updates have focused on subsequent Advisory Committee on Immunization Practice (ACIP) statements regarding immunizations for adults and the supporting literature presented by ACIP. This guideline is based on ACIP statements through January 2009.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Levels of Evidence Reflect the Best Available Literature in Support of an Intervention or Test

A. Randomized controlled trials
B. Controlled trials, no randomization
C. Observational trials

D. Opinion of expert panel

METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses
Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Conclusions were based on prospective randomized clinical trials.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Not stated

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Strength of Recommendation

I = Generally should be performed

II = May be reasonable to perform

III = Generally should not be performed

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

The guideline was reviewed at clinical conferences or grand rounds meetings of divisions and departments to which the content is most relevant. This guideline was reviewed at meetings of faculty in Family Medicine and General Medicine. For periodic major updates, the University of Michigan Health System (UMHS) Executive Committee on Clinical Affairs performs a final review prior to institutionally endorsing the guideline. For this interim annual update the guideline was endorsed by the UMHS Guideline Oversight Committee.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Note from the National Guideline Clearinghouse (NGC): The following key points summarize the content of the guideline. Refer to the original guideline document for additional information.

The strength of recommendation (I-III) and levels of evidence [A-D] are defined at the end of the "Major Recommendations" field.

<table>
<tr><th>Vaccine/Doses</th><th>Priority Populations</th></tr>
<tr><td colspan="2">Hepatitis A Vaccine

Note: For combined hepatitis A and B vaccination, use Hepatitis A/Hepatitis B Vaccine (Twinrix Adult) three doses at 0, 1, and 6 months or accelerated schedule[1] if indicated.

[1]Accelerated dosing schedule: Hepatitis A/Hepatitis B Vaccine (Twinrix Adult):

Three doses in 3 weeks (0, 7days, 21-30 days); booster at 12 months. Consider for:

• Emergency first-care responders
• Individuals preparing to travel to high-risk areas on short notice
• Those with risk factors for hepatitis such as human immunodeficiency virus (HIV) and sexually transmitted diseases</td></tr>
<tr><td>Two doses at 0 and 6—18 months</td><td>• Persons with chronic liver disease
• Persons who receive clotting factor concentrates
• Men who have sex with men, illicit drug-users
• Travelers to countries where there is higher or intermediate hepatitis A virus (HAV) endemicity
• Persons with occupational risk who work with HAV-infected primates or HAV in a research lab</td></tr>
<tr><td colspan="2">Hepatitis B Vaccine Series

Note: For combined hepatitis A and B vaccination, use Hepatitis A/Hepatitis B Vaccine (Twinrix Adult), three doses at 0, 1 and 6 months or accelerated schedule[1] if indicated.

[1]Accelerated dosing schedule: Hepatitis A/Hepatitis B Vaccine (Twinrix Adult):

Three doses in 3 weeks (0, 7days, 21-30 days); booster at 12 months. Consider for:

• Emergency first-care responders
• Individuals preparing to travel to high-risk areas on short notice
• Those with risk factors for hepatitis such as HIV and sexually transmitted diseases</td></tr>
</table>

Vaccine/Doses	Priority Populations
Three doses at 0, 1, and 6 months (For immunocompromised patients and hemodialysis patients, increase dose to 40 micrograms.)	• Individuals with multiple sex partners • Men who have sex with men • End-stage renal disease (ESRD) and hemodialysis patients (early in disease) • Intravenous (IV) drug users and their sexual partners • Immigrants from and travelers to high risk areas • Persons with recent sexually transmitted diseases (STDs) (see original guideline document for further details) • Persons with human immunodeficiency virus(HIV)/acquired immunodeficiency disease syndrome (AIDS) • Healthcare workers/public safety workers/students exposed to blood • Clients and staff of institutions for the developmentally disabled and correctional facilities • Persons seeking protection against hepatitis B virus (HBV) • Household contacts & sexual partners of persons with chronic hepatitis B virus (HBV) infection
No routine booster	Immunity from the vaccine series is currently felt to be lifelong.
Herpes Zoster Vaccine **Note**: Live virus vaccine (This vaccine may not be covered by all payers or all Medicare Part D policies. Patients should confirm coverage.)	
One dose	• Adults, ≥ 60 and old, whether or not they report a prior episode of herpes zoster. Persons with chronic medical conditions may be vaccinated, unless a contraindication precaution exists.
Human Papilloma Virus (HPV) Vaccine, Quadrivalent **Note**: In women of child bearing age, avoid pregnancy for at least 4 weeks after immunization	
Three doses at 0, 2, and 6 months. Minimum interval of 24 weeks between doses 1 and 3.	• Females ≤ 26 years old who have not received the vaccine or completed the series. If a woman turns 27 years old after the first dose is administered but before the third dose is given, complete the series using the recommended intervals between doses.

Vaccine/Doses	Priority Populations
Booster uncertain	Efficacy beyond 5 years is presently unknown.
Influenza Vaccines	
Initial dose: Inactivated (injectable)	• Adults ≥50 years old [*B**] • Persons with chronic illnesses (e.g., cardiovascular, pulmonary, renal, metabolic, sickle cell disease, immunosuppression/HIV, disorders increasing risk of aspiration), asplenia • Residents of long-term care facilities [*B**] • Women who are pregnant • Health care workers, including home care and long-term care workers [*A**] • Household contacts and out-of-house caregivers of children less than 6 years old or adults ≥ 65 years old • Others who can transmit influenza to a high risk population
Initial dose: Live attenuated (intranasal)	• For non-pregnant healthy persons <50 years old in priority populations, live attenuated vaccine may be used as an alternative to inactivated vaccine. (Non-priority healthy persons <50 years old may receive either vaccine if supply allows.)
Revaccinate annually	• Persons eligible under criteria for initial immunization vaccine
Measles, Mumps, Rubella (MMR) Vaccine (use combined MMR vaccine) **Note**: Live virus vaccine	
Initial dose	• No evidence of immunity* to measles, to mumps, or (if woman of childbearing age) to rubella • Consider giving initial dose to unvaccinated health-care workers born before 1957 who do not have other evidence of mumps immunity* * Evidence of immunity: (a) documentation of MMR vaccination requires 2 doses for measles, 1 dose for rubella or mumps (b) laboratory evidence of immunity, (c) documentation of physician diagnosis or (d) born before 1957 (age exceptions: rubella immunity not assumed for women of child-bearing age who could become pregnant; measles and mumps immunity possibly not assumed for health care workers)

Vaccine/Doses	Priority Populations
Second dose at ≥1 month	• Health care workers (for measles, mumps) • College students (for measles, mumps; first dose may be required before start classes) • Travelers to foreign countries (for measles, mumps) • Recently exposed to measles or are in an outbreak setting • Previously vaccinated with killed measles vaccine, or between 1963—1967 with an unknown measles vaccine • In age group affected during a mumps outbreak
Meningococcal Vaccine (Use meningococcal conjugate [Menactra™] for adults <55 years and meningococcal polysaccharide [Menomune®] for those >55 years)	
Initial - one dose	• College freshman living in dormitories • Persons who have functional or anatomic asplenia and terminal complement component deficiencies • Travelers to sub-Saharan Africa from Senegal in the west to Ethiopia in the east, especially from December to June • Microbiologists routinely exposed to isolates of Neisseria meningitidis
Revaccinate: once every 3 to 5 years	• The above persons if indications still exist for vaccination and the last vaccination was given with Meningococcal polysaccharide • No need to revaccinate if previously vaccinated with meningococcal conjugate (Menactra™)
Pneumococcal Polysaccharide Vaccine	
Initial dose	• All adults >65 years old [*B*] • Persons 19 through 64 years old who smoke cigarettes of have asthma • Residents of nursing home and long-term care facilities • Persons with chronic illness (e.g., cardiovascular, pulmonary), diabetes, kidney or liver disease, alcoholism, cerebrospinal fluid leak, cochlear implants, sickle cell disease, asplenia and other immunosuppressive conditions, chemotherapy, steroid use - see original guideline document) • Native Americans and Native Alaskans younger

Vaccine/Doses	Priority Populations
	than 65 years old who are living in areas where there is an increased risk of invasive pneumococcal disease
Revaccinate once ≥5 years after initial dose only for the following high risk patients **Note**: Maximum of 2 doses PPSV23 in a lifetime	• Age: persons ≥65 years old, if initial vaccine was given ≥5 years previously at age <65 years old [*A**]. • Chronic disease: highest risk for pneumococcal infection or rapid decline in antibody (e.g., functional or anatomic asplenia, sickle cell disease, transplant recipient, HIV, nephrotic syndrome, chronic renal failure, immunosuppressed)
Tetanus, Diphtheria, Pertussis Vaccines (Td/Tdap) (primary series assumed)[2] [2] If primary series not given: 3 doses Td at 0, 4 weeks, and 7—12 months	

Revaccinate every 10 years	• All patients [*A**]
	• A one-time dose of tetanus, diphtheria, and pertussis (Tdap) should be given to:
	  • Postpartum women, close contacts of infants <12 months old, and health care workers with at least a 2 year interval from previous tetanus-diphtheria (Td) vaccine
	  • Adults <65 years old who have not previously received a dose of Tdap and are due for a tetanus vaccine (for booster or wound management)

Revaccinate in ≥5 years	• Patients with wounds (other than clean or minor wounds)
Varicella Vaccine **Note**: Live virus vaccine	
Two doses at 0 and ≥4 weeks	• All non-pregnant adults without evidence of immunity to varicella[3]. Give special consideration to those who have close contact with persons at high risk for severe disease (e.g., healthcare workers and family contacts of immunocompromised persons) or are at high risk for exposure or transmission (e.g., teachers of young children; child care workers; college

Vaccine/Doses	Priority Populations
	students; residents and staff of institutional settings, including correctional facilities; military personnel; international travelers; and non-pregnant women of childbearing age). [3] Evidence of immunity to varicella: (a) documentation of 2 doses of varicella vaccine; (b) U.S.-born before 1980 (except for immunocompromised, health-care workers and pregnant women); (c) history of diagnosis of varicella by a health-care provider; (d) history of herpes zoster based on health-care provider diagnosis; or (e) laboratory evidence of immunity or laboratory confirmation of disease. (see original guideline document for further details)

Definitions:

Strength of Recommendation

I = Generally should be performed

II = May be reasonable to perform

III = Generally should not be performed

Levels of Evidence

A. Randomized controlled trials
B. Controlled trials, no randomization
C. Observational trials
D. Opinion of expert panel

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for some of the recommendations (see "Major Recommendations").

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Appropriate and timely administration of routine adult immunizations

POTENTIAL HARMS

- No documented cases of congenital rubella syndrome have resulted from rubella vaccination in early pregnancy, but this practice is not recommended.
- The most frequently reported adverse events following herpes zoster vaccination were injection site reactions and rashes.

CONTRAINDICATIONS

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- *Herpes Zoster Vaccine*, because herpes zoster vaccine is a live attenuated virus the following persons should not get herpes zoster vaccine:
    - Those with a life-threatening allergic reaction to gelatin, the antibiotic neomycin, or any other component of shingles vaccine
    - Those who have a weakened immune system because of: human immunodeficiency virus (HIV), acquired immunodeficiency disease syndrome (AIDS) or another disease that affects the immune system, treatment with drugs that affect the immune system, such as steroids, cancer treatment such as radiation or chemotherapy, a history of cancer affecting the bone marrow or lymphatic system, such as leukemia or lymphoma
    - Those with active, untreated tuberculosis
    - Women who are pregnant, or might be pregnant. Women should not become pregnant until at least three months after getting herpes zoster vaccine.
- *Human Papilloma Virus Vaccine, Quadrivalent*:
    - Not recommended for use in pregnancy
    - People with a history of immediate hypersensitivity to yeast or to any vaccine component should not receive the vaccine.
    - People with moderate or severe acute illnesses should be deferred from receiving the vaccine until after the illness improves.
- *Influenza Vaccine*:
    - Patients with severe egg allergy or previous allergy/anaphylaxis to influenza vaccine should not receive the flu vaccine.
    - Caution should be taken in those with a previous history of Guillain-Barré syndrome.
- *Measles, Mumps and Rubella (MMR) and Varicella*:
    - Pregnancy should be avoided for 4 weeks following immunization as this is a live vaccine.
    - The combination vaccine should not be used for a patient who has a contraindication to an individual component.
    - Do not give immune globulin (IG) products and MMR simultaneously. If unavoidable, give at different sites and revaccinate or test for seroconversion in 3 months. If MMR is given first, do not give IG for 2 weeks. If IG is given first, the interval between IG and measles vaccination depends on the product, the dose, and the indication.
- *Tetanus, Diphtheria and Pertussis (Td/Tdap)*: Whenever possible, Td should be deferred during pregnancy and Tdap substituted in the immediate postpartum period.
- *Varicella Vaccine* is contraindicated in:
    - Pregnant women or women that may become pregnant within 4 weeks
    - Immunocompromising conditions including HIV with CD4 $\leq$ 200, congenital immunodeficiencies, leukemia, lymphoma; generalized

malignancies; cerebrospinal fluid leaks; therapy with alkylating agents, antimetabolites, radiation or high dose (> 20 mgs) long-term corticosteroids

- Patients who had received blood within the previous 5 months (except washed red blood cells) or plasma transfusions, immune globulin (IG), or varicella zoster immune globulin (VZIG). In addition, IG and VZIG should not be administered for 3 weeks after vaccination unless the benefits exceed those of vaccination.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

These guidelines should not be construed as including all proper methods of care or excluding other acceptable methods of care reasonably directed to obtaining the same results. The ultimate judgment regarding any specific clinical procedure or treatment must be made by the physician in light of the circumstances presented by the patient.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

IMPLEMENTATION TOOLS

Staff Training/Competency Material

For information about availability, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Staying Healthy

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

University of Michigan Health System. Adult immunizations. Ann Arbor (MI): University of Michigan Health System; 2009 Feb. 10 p. [8 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2004 May (revised 2009 Feb)

GUIDELINE DEVELOPER(S)

University of Michigan Health System - Academic Institution

SOURCE(S) OF FUNDING

University of Michigan Health System (UMHS)

GUIDELINE COMMITTEE

Immunizations Guideline Team

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Team Leads: Margie C Andreae, MD, Pediatrics and Communicable Diseases; Candia B Laughlin, RN, MS, Ambulatory Care Nursing Administration

Team Members: Mary K Barry-Bodine, RN, BSN, Nursing, Health Centers; Susan G Blitz, MD, MPH, General Medicine; Sherry L DeLoach, PharmD, Pharmacy; Susan F Engert, MD, MPH, Pediatrics and Communicable Diseases; Susan D Garrett, CPhT, Pharmacy; Jean M Malouin, MD, MPH, Family Medicine; Linda M McGrath, BSN, RN, UMHHC Immunization Coordinator

Consultant: Sandro K Cinti, MD, Infectious Diseases

UMHS Guidelines Oversight Team: William E Chavey, MD; R. Van Harrison, PhD

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

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Team Member	Relationship	Company
Margie Andreae, MD	(none)	
Mary Barry-Bodine, RN, BSN	(none)	
Susan Blitz, MD, MPH	(none)	
Sherry DeLoach, PharmD	(none)	
Susan Engert, MD, MPH	(none)	
Susan Garrett, CPhT	(none)	
Candia Laughlin, RN, MS	(none)	
Jean Malouin, MD, MPH	(none)	
Linda McGrath, BSN, RN	(none)	
Sandro K. Cinti, MD	(none)	

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GUIDELINE AVAILABILITY

Electronic copies: Available for download (in Portable Document Format [PDF]) from the University of Michigan Health System Web site.

AVAILABILITY OF COMPANION DOCUMENTS

Continuing Medical Education (CME) information is available from the University of Michigan Health System Web site.

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI on October 12, 2004. The information was verified by the guideline developer on October 22, 2004. This summary was updated by ECRI on October 5, 2005 following the U.S. Food and Drug Administration (FDA) advisory on Menactra (Meningococcal Conjugate Vaccine A, C, Y, and W135). This NGC summary was updated by ECRI on February 23, 2006. The updated information was verified by the guideline developer on March 17, 2006. This summary was updated by ECRI on October 25, 2006 following the updated FDA advisory on Menactra (Meningococcal Conjugate Vaccine). This NGC summary was updated by ECRI Institute on July 9, 2007. The updated information was verified by the guideline developer on July 23, 2007. This NGC summary was updated by ECRI Institute on July 24, 2008. The updated information was verified by the guideline developer on August 15, 2008. This NGC summary was updated by ECRI Institute on July 8, 2009. The updated information was verified by the guideline developer on July 21, 2009.

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